ATTACHMENT 4-4

# 510(k) Summary per 21 CFR 807.92

DEC 19 2013

| | |
|---|---|
| Submitter | Nipro Medical Corporation<br>3150 NW 107th Avenue<br>Miami, FL 33172<br>FDA Establishment #: 1056186 |
| Contact Person | Jessica Oswald-McLeod<br>Phone: 305-599-7174<br>Fax: 305-592-4621 |
| Date of Preparation | November 21, 2013 |
| Device Trade Names | Nipro ELISIO™-H Hemodialyzer |
| Device Classification Name | High permeability hemodialysis system per 21CFR 876.5860 |
| Common Name | Hemodialyzer |
| Substantial Equivalence | K122347 ELISIO™-H Hemodialyzer<br>K002761 Fresenius Hemoflow<br>K926005 Fresenius Hemoflow<br>K082414 Fresenius Optiflux |
| Device Description | The ELISIO-H hemodialyzers are medical devices used as an artificial kidney system for the treatment of patients with renal failure. During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment.<br><br>The ELISIO-H dialyzers are composed of polyethersulfone fiber and are available in various sizes, which are differentiated by membrane surface area. |

| | |
|---|---|
| Intended Use | Hemodialysis with an ELISIO™-H hemodialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.<br><br>The device is for prescription use only. This product is intended for single use only. The performance properties of reused dialyzers have not been established. |
| Technological Aspects | Both the original sizes of the ELISIO-H hemodialyzer and the new family members (sizes -90H and -250H) are composed of polyethersulfone fiber. The membrane composition and the housing case composition are identical between the existing sizes of the ELISIO dialyzers and the new sizes. The modification is the inclusion of two additional family members to the ELISIO-H product line.<br><br>Non-clinical studies included those for analyte clearance (urea, creatinine, phosphate, Vitamin $B_{12}$, inulin), ultrafiltration coefficient and pressure drop and are included in product labeling. Results of bench studies establish substantial equivalence to Fresenius hemodialyzer performance. |
| Conclusion | Testing performed on the ELISIO-H dialyzers indicates that they are safe, effective and perform as well as the legally marketed device models, when used in accordance with the instructions for use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

Nipro Medical Corporation
Regulatory Affairs
% Carolyn K. George
Consultant
3150 NW 107th Avenue
Miami, FL 33172

Re: K131381
Trade/Device Name: ELISIO™-H Hemodialyzer
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: November 21, 2013
Received: November 26, 2013

Dear Carolyn K. George,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number:** K131381

**Device Name:** ELISIO™-H hemodialyzer

**Indications for Use:**

Hemodialysis with an ELISIO™-H hemodialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

The device is for prescription use only.

This product is intended for single use only. The performance properties of reused dialyzers have not been established.

| Prescription Use _X_ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
2013.12.18 15:32:53 -05'00'